



NewsBREAK | Nov. 4

CY2023 Physician Fee Schedule Final Rule – Effective Jan. 1, 2023

- **Discarded Amounts.** Manufacturers must provide refunds to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. Modifiers indicating discarded amounts are required on all separately paid single-use vial or single-use package drug claims. However, refunds are limited to single-source products. The rule clarifies that the “unused and discarded” amount is any amount that is not part of the dose and not intended to have a therapeutic effect.
- **Refundable Single-Dose Container/Single-use Package Drug.** All NDCs assigned to a drug’s billing and payment code must be single-dose containers; a single NDC that is not single-use/single-dose brings the entire product outside of the definition. Self-administered DME drugs are excluded since beneficiaries do not report wasted amounts.
- **CMS Reporting to Manufacturers.** CMS will send annual reports to manufacturers with discard information for each calendar quarter. Timing of the initial reports and other details are not yet finalized due to potential interaction with rebate payments under the Inflation Reduction Act (IRA). However, a preliminary report for Q1 and Q2 of 2023 will be sent by Dec. 31, 2023.
- **Refund Amount and Applicable Percentage.** The rule finalized higher applicable percentage of 35% for drugs reconstituted with hydrogel. Jelmyto® is the only product that qualifies.
- **Refund Interaction with Government Price Reporting Requirements.** The rule clarifies that discarded amount refunds are excluded from ASP, AMP, and Best Price reporting.

CY 2023 OPPS Final Rule – Effective Jan. 1, 2023

- **340B Payment Reductions.** Section 340B of the Public Health Service Act (340B) allows covered entities to purchase certain covered outpatient drugs from manufacturers at discounted prices. For CY 2023, in light of the Supreme Court’s decision in *American Hospital Association v. Becerra* (No. 20-1114, 2022 WL 2135490), CMS is finalizing a general payment rate of average sales price (ASP) plus 6% for drugs and biologicals acquired through the 340B Program.

See the final rules for additional requirements.

More on This Topic

- [CY2023 Physician Fee Schedule Final Rule](#)
- [Physician Fee Schedule Fact Sheet](#)

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- [CY 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule](#)
 - [Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Fact Sheet](#)

For questions, please reach out to [Tyler Thorne](#).

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